CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (Proposition 65)

NOTICE TO INTERESTED PARTIES August 19, 2005

CHEMICALS LISTED EFFECTIVE **August 19, 2005**AS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER

The Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency is adding "estrogens, steroidal" to the list of chemicals known to the state to cause cancer for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code section 25249.5, Proposition 65). The listing of "estrogens, steroidal" is effective **August 19, 2005.**

Health and Safety Code section 25249.8(a) requires that certain substances identified by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP), as described in Labor Code sections 6382(b)(1) and (d), be included on the Proposition 65 list. Labor Code section 6382(b)(1) references substances identified as human or animal carcinogens by IARC, and Labor Code section 6382(d) references substances identified as carcinogens or potential carcinogens by IARC or NTP. Steroidal estrogens were identified by NTP as known to be human carcinogens.

The basis for the listing of "estrogens, steroidal" on the Proposition 65 list was described in OEHHA's Request for Comments on Proposed Listing of "Estrogens, Steroidal" As Known to Cause Cancer published in the June 24, 2005, issue of the California Regulatory Notice Register (Register 2005, No. 25-Z). In 2002, NTP published the Tenth Report on Carcinogens. In this report, NTP concluded "steroidal estrogens" are known to be human carcinogens based on sufficient evidence of carcinogenicity in humans, which indicates a causal relationship between exposure to steroidal estrogens and human cancer." The NTP has previously listed conjugated estrogens as known to be human carcinogens and some individual non-conjugated steroidal estrogens (i.e., estradiol-17β, estrone, ethinylestradiol and mestranol) as reasonably anticipated to be human carcinogens, beginning in the Fourth Annual Report on Carcinogens (1985). In the Tenth Report on Carcinogens, NTP states, "This listing of steroidal estrogens supersedes the previous listing of specific estrogens in the Report on Carcinogens and applies to all chemicals of this steroid class." OEHHA received no public comments in consideration of the listing of these chemicals. [NOTE: Although this notice announces the listing of steroidal estrogens as a class, the effective listing dates for the specific steroidal estrogens (conjugated estrogens, estradiol-17β, estrone, ethinylestradiol and mestranol) already listed as causing cancer under Proposition 65 remain unchanged.]

OEHHA analyses of dose-response data to establish the no significant risk levels (NSRLs) for these chemicals under Proposition 65 have not been conducted. The priority status of the development of such analyses will be announced in a future OEHHA *Proposition 65 Status Report for Safe Harbor Levels*, available at http://www.oehha.ca.gov/prop65.html.

A complete, updated Proposition 65 list is published elsewhere in this issue of the *California Regulatory Notice Register*.

Cancer

Chemical	CAS No.	Toxicological Endpoint	Listing Mechanism ¹
Estrogens, steroidal		Cancer	LC

¹ Listing mechanism:

LC – "Labor Code" mechanism (Labor Code sections 6382(b)(1) and (d))